THE ANCILLARY-CARE RESPONSIBILITIES OF MEDICAL RESEARCHERS

An Ethical Framework for Thinking about the Clinical Care that Researchers Owe Their Subjects

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Researchers do not owe their subjects the same level of care that physicians owe patients, but they owe more than merely what the research protocol stipulates. In keeping with the dynamics of the relationship between researcher and subject, they have limited but substantive fiduciary obligations.

Malaria researchers may detect that their juvenile subjects are suffering from schistosomiasis, a serious parasitic disease common in many malarial areas. Do the researchers have a responsibility to treat the schistosomiasis? Functional brain scans collected for research purposes may contain information that would enable the appropriate specialist to diagnose a subject with a condition unrelated to what is being studied. Is there a responsibility to have images that were collected for research purposes read diagnostically?

Such questions about researchers' responsibilities to provide ancillary clinical care arise pervasively, yet there is an almost total absence of guidance.

Providing guidance requires confronting some very basic questions about the relationship between researcher and subject. What sort of care, if any, ought medical researchers provide their subjects, beyond what is necessary to implement a study's design safely and validly? Ought they respond to their subjects' needs as fully as a physician would to a patient's? If they owe less than that, what ethical principles explain the proper bounds of researchers' ancillary-care responsibilities? To address these questions, we develop an ethical framework that will help individual investigators, institutional review boards, and policymakers anticipate the ancillary-care responsibilities that will arise during a given study and ensure that enough research funds are earmarked to meet them. This framework is intended as a first step in what will need to be an ongoing process of working out further guidance.

Henry S. Richardson and Leah Belsky, "The Ancillary-Care Responsibilities of Medical Researchers: An Ethical Framework for Thinking about the Clinical Care that Researchers Owe Their Subjects," *Hastings Center Report* 34, no. 1(2004): 25-33.

What Is Ancillary Care?

Defining "ancillary care" in the context of clinical research requires examining the rationale of the care. Ancillary care is that which goes beyond the requirements of scientific validity, safety, keeping promises, or rectifying injuries. Stabilizing subjects to get them on a protocol is not ancillary care, since it is required for carrying out the study. Monitoring subjects' drug interactions also does not count as ancillary care, since it is typically required in order to minimize risks caused by the study. Two additional rationales for care need to be excluded. In order to recruit and enroll a sufficient number of subjects, it is sometimes pragmatically necessary to promise potential subjects extra care that would not be required by science or safety. Of course, anything can be promised; but we are examining the ethical reasons to provide extra care whether one has promised it or not. Further, even when careful safety measures are in place, research participation can cause injury to subjects. Although participants sustaining research injuries are generally owed care, we set compensation for research injury aside as a separate ethical question.

Ancillary care, then, is care not required by sound science, safe trial conduct, morally optional promises, or redressing subject injury. This ethically neutral definition allows us to pursue the ethical question of what sorts of extra clinical care researchers ought to provide and to raise (and reject) the hypothesis that the extra care they ought to provide is just what is "research-related." It allows that any given instance of "ancillary care" may or may not be morally required (or even morally permissible) and may or may not be "research-related."

The General Duty of Rescue

Before we come to the responsibilities that are specially incumbent on clinical researchers, we should note that all moral agents, whether individual or collective, have duties to rescue those in need. For instance, everyone has a duty to help a person who is in need and whom no one else can help, at least when one can provide the help without serious sacrifice or risk.[1] Even if one's ability to help is not strictly unique, an urgent need can generate a duty to help when it is predictable that no one else will.[2] These duties are quite general and generate moral demands not only on individual researchers' medical skills but also on the collective financial and political resources of the research team and its sponsors.

In the setting of medical research, a unique ability to help can arise in various ways. One way it can arise is through a combination of geography and poverty. Researchers conducting a clinical study in remote areas within developing countries may have responsibilities to plan for or provide ancillary care just because there may be no other doctors or hospitals in the area, or none who will help one's subjects. In such cases, researchers have at least the responsibility to provide cheap and simple aid to those who urgently need it. An example of this type would be providing antihelminthic drugs to de-worm children threatened with malnutrition.

But although the duties of rescue have important implications for medical researchers, especially those working in impoverished settings, we set them aside here in order to turn to those responsibilities that are specially incumbent upon researchers. The researchers' responsibilities we identify supplement the duties of rescue. In fact, the duties of rescue establish a basic orientation that ought to guide how the more specific responsibilities of researchers are interpreted in practice.

Toward a Conception of Researchers' Responsibilities

There are two polar ethical positions on the provision of ancillary care. Neither recognizes the existence of researchers' responsibilities for ancillary care as such, and neither is tenable.[3] One of these views casts researchers as personal physicians and research subjects as patients. It suggests that clinical researchers should provide subjects all ancillary care that a physician would provide a similarly situated patient. The moral impulse behind this view, which constructs the responsibilities of researchers on the basis of their inhabiting another role, namely that of physician, is generous but flawed. For one thing, clinical researchers may not be physicians. For another, this view of researchers confounds or elides the roles of personal physician and clinical researcher in a way that threatens to exacerbate the therapeutic misconception.[4] Although this approach holds that it would not be a misconception to expect that a researcher might provide some ancillary care, there remains room for subjects to misconceive the purpose of any experimental treatment or drug. The scientific purpose of an experimental protocol often constrains clinical possibilities, and this approach would encourage subjects to misunderstand that point.

Because modeling researcher responsibilities on those of personal physicians ignores the crucial fact that the defining goal of medical research is the generation of generalizable knowledge and not the promotion of individual patients' health,[5] this view requires too much ancillary care. This defining goal of research can conflict with the provision of ancillary care in two main ways: First, provision of ancillary care can divert money and human resources away from the research effort. For instance, requiring AIDS researchers to provide costly treatments for AIDS would make much AIDS research less feasible. Such conflicts can also show up on a smaller scale. Second, provision of ancillary care can require dropping subjects from a protocol. Ancillary care can interfere with a research protocol if, for example, the individualized care would mean departing from protocol dosages or if it would confound the analysis of study outcomes. The

need to maintain study power explains why it may be justified to postpone care that is not urgently needed rather than take a subject off protocol.

The other polar view conceives of researchers as pure scientists and research subjects simply as volunteers. Accordingly, it denies that there are fundamental reasons for providing care apart from science, safety, promise, and injury. This view yields obviously unacceptable conclusions about care for conditions that are, in some sense, "research-related." For example, consider the situation of indigent subjects in AIDS drugs trials who do not have other health care providers and are experiencing discomfort that results from their underlying condition, not from the experimental treatment.[6] Suppose that treating the discomfort would not interfere with the study, but that it is so minor that doing so is required neither for safety nor by the duty of rescue. Even so, the researchers ought to provide at least straightforward, immediate means for relieving discomfort resulting from the condition under study, whether or not they had promised to do so.

These intuitive grounds for rejecting polar positions are powerful, but barely begin to suggest any principles governing when ancillary care ought to be provided. It would not help to think of clinical researchers as alternately wearing physician and scientist "hats." To be sure, sometimes a researcher is also, independently, a subject's physician. In such cases, the research relationship will not cancel ancillary responsibilities based in the physician-patient relationship. In other cases, however, researchers have no professional relationship with the subjects outside of the research. To develop definite and stable guidelines for ancillary care, we concentrate on the latter, simpler case. Our aim is to construct a conception of the clinical researchers' responsibilities as such. To that end, we turn to the concept of *entrustment*.

The partial and limited entrustment described in the law concerning *bailment* fits the situation of medical researchers. Researchers are not trustees, yet since researchers take on a partial, limited entrustment for certain aspects of their subjects' health, they do owe them care.

The Partial-Entrustment Model of the Researcher-Subject Relationship

The physician-patient relationship has a strongly fiduciary aspect: personal physicians act as trustees who are authorized to pursue their patients' health according to their best judgment and who are expected to do so with undivided loyalty.[7] Since, as we have noted, researchers owe loyalty also to the scientific endeavor, they are not fiduciaries for subjects' health. On the researcher-as-pure-scientist model, by contrast, the leading legal metaphor is *contract*: investigators are required to provide only those kinds of care they have voluntarily agreed in advance to provide, there being no moral imperative for them to undertake any ancillary care. Is there a middle ground between fully entrusting one's health to someone, as one does to one's personal physician, and not entrusting one's health at all? Of course there is: it involves *partially* entrusting one's health. What does that mean?

There is a broad range of entrustment relationships, of which fiduciary relationships are an important but extreme instance. Entrustment relationships impose special duties of care, incumbent on those in whom trust is reposed. The primary facts that constitute an entrustment relationship are not psychological: they do not refer to the states of mind—the expectations or beliefs—of either party. Rather, relationships in which courts have recognized some degree of entrustment obligation possess two main elements: discretion and vulnerability. These two elements are identifiable without any direct reference to the parties' expectations, presumptions, or hopes. The *discretion* we refer to results when one person ("the beneficiary") authorizes another ("the entrusted person") to employ significant personal judgment in deciding how to act on the behalf of something the beneficiary cares about. *Vulnerability* refers to the fact that how the entrusted person chooses to exercise this discretion may considerably affect the beneficiary's well-being.[8]

Discretion and vulnerability give rise to two dimensions that contribute to how full an entrustment is. Entrustments may involve varying degrees of discretion and may give the one to whom discretion is granted varying degrees of influence on the beneficiary's well-being. Even quite minor discretion can by happenstance create life-and-death vulnerability. More important to the extent of any obligations that arise is how wide the entrusted person's discretion is. Only those who have broad discretionary control over someone's well-being and who are forbidden conflicting loyalties will count as trustees and

take on a trustee's fiduciary obligation to decide matters solely on the basis of the beneficiary's best interests. In financial trusteeships, for instance, the delegation of discretion goes to the point that the beneficiary renounces the power to second-guess the trustee's judgment. The ethics of the doctor-patient relationship takes a first, major step away from full entrustment by renouncing paternalism. Further steps away from full entrustment can be taken by narrowing the range of powers that are conferred, even if only implicitly, on the entrusted person.

A legal name for this kind of intermediate, limited entrustment is *bailment*. In the old common law, a bailee is someone who accepts custody of some particular good and is entrusted to look out for it only in limited ways.[9] A typical example of bailment occurs when an auto shop takes custody of your car. In contrast to a simple contractual arrangement in which each party's rights and duties are spelled out in advance, the auto shop (the bailee) has, in addition to the contractual duty to fix your car's dents, a responsibility to exercise reasonable care and due discretion in taking positive steps to protect your car from various other hazards. Rescuing the car from a fire that breaks out next door would be one example of a positive step for which the auto shop is responsible.[10] (Tickets from parking garages often will say "no bailment created" in an attempt to evade such responsibility.) In contrast to trusteeships, the responsibility of due discretion in bailment does not arise from an explicit, broad grant of discretion ("do whatever you need to do to promote my financial well-being"). Rather, it has a dual source: an authorization to take custody of some valued item, coupled with the bailee's superior position to judge how best to protect that item.[11]

The partial and limited entrustment described in the law concerning bailment fits the situation of medical researchers. As trustees for their patients' health, physicians owe them a wide range of care; for instance, they owe patients who smoke an anti-smoking lecture. Since researchers are not trustees, they do not owe their subjects that lecture unless they are doing pulmonary or smoking-related research. Yet since researchers take on a partial, limited entrustment for certain aspects of their subjects' health, they do owe them care such as simple, otherwise unobtainable management of discomfort, whether or not that has been contractually promised.[12] As in bailment, generally, this limited entrustment of aspects of health to researchers arises from a combination of special authorizations and superior knowledge.

Subjects do not empower researchers to do whatever is necessary to promote their health, yet they do grant researchers certain special authorizations. Subjects do this by consenting to waive some of their normal rights. By consenting to be involved in a trial, they implicitly or explicitly authorize researchers to collect confidential medical information about them; to touch, poke, or cut them; to collect bodily samples from them; or to undertake medical procedures on them. In addition, they may agree to give up some of their normal control over their own health, as happens if they agree to participate in blinded studies or in psychiatric drug trials involving washout phases. In these ways, subjects transfer rights to the researchers.

Discretion naturally arises from these ways that the informed consent process transfers rights to researchers. The complexity of medicine and the specialized training required to master aspects of it will generally put researchers in a far superior position to understand the health import of any information that their interventions and tests yield. It would be futile and misguided to attempt to bypass researchers' professional judgment by writing an informed consent contract that spelled out exactly how researchers will respond to every foreseeable finding—and many findings are not even foreseeable. Having been authorized to deal with certain aspects of their subjects' health, researchers will thus inevitably be put in a position of making discretionary judgments about how to protect and promote it.[13] More specifically, researchers have the discretionary power to respond, or not to respond, to any finding about an individual that they reach by exercising the special authorizations they have been granted to gather confidential medical information.

From Discretion to Responsibility

The combination of authorization and vulnerability does not alone suffice to generate an entrustment obligation, however.[14] There is an additional, normative condition for such responsibility. In the context of clinical research, as in our paradigmatic case of bailment, this normative constituent is not found in the purpose of the relationship. In clinical research, as in giving one's car over to the body shop, the purpose of the interaction is not to promote or preserve the entrusted good (the car, the subject's health), but to pursue an ulterior aim (to get the dent fixed, to generate generalizable knowledge). The normative condition that triggers entrustment responsibility in clinical research is the general applicability in the course of research of three moral obligations that pertain to subjects' vulnerability and researchers' discretion: compassion, engagement, and gratitude. Since these duties help explain why researchers have limited entrustment responsibilities and not simply a set of discretionary powers they may freely exploit, we refer to them as providing the rationale for these responsibilities.

The general duty to act compassionately toward the needy, vulnerable, and dependent bears specially on subjects' vulnerability to how researchers exercise the discretion that the subjects' authorizations provide them with. In general, acting compassionately means being attentive

and reasonably responsive to an individual's needs and perspectives.[15] In the research context, the general duty of compassion is particularly relevant when subjects are ill. Beyond that, however, the vulnerability generally created by putting researchers in the position of exercising their discretion is likely to mean that almost any subject is deserving of at least a modicum of compassionate attentiveness.

To what ends should researchers exercise this discretion? Although the organizing purpose of clinical trials is to generate knowledge rather than to promote the health of their subjects, it is morally imperative that researchers engage with patients as whole people, as opposed to treating them as mere carriers of chemicals or conditions.[16] Thus *engaging* means acknowledging a relationship with the patient as a person that is not narrowly delimited along the lines of one's medical specialty or by the extent of research interaction. Just as oncologists must look beyond treating the cancer to the patient with the cancer,[17] investigators must look beyond the focus of their research and beyond a narrow construal of what their medical skills have to offer. They must recognize when they have developed broader knowledge about a subject that is essential to a subject's care, and they must be willing to use this knowledge on the subject's behalf. In short, the subjects, as embodied persons, must be treated as ends that orient researchers' discretionary judgment.

Researchers may also owe subjects gratitude for having received the permission necessary to conduct a trial. When subjects join research protocols, they willingly enter into a vulnerable relationship from which they may never benefit. Since researchers both rely on and benefit from volunteers' willingness to participate, they generally have a duty of gratitude to cooperative subjects.[18] Such a debt is not discharged just because a subject's particular illness or condition improves as a result of the research protocol, as it may also require an investigator to remain conscious of a subject's other health needs or concerns and be willing to satisfy them when appropriate.

The entrustment responsibilities incumbent on researchers are limited in both scope and strength: not all types of medical care that a subject might need are part of the researchers' responsibility, and in some contexts, the rationale for providing ancillary care is insufficient to justify spending the researchers' time and resources on it.

These duties of compassion, engagement, and gratitude help to explain why researchers, having been granted discretionary power over aspects of their subjects' health, take on moral responsibilities toward their subjects. These duties provide a moral rationale for a limited and partial set of responsibilities that are well described by saying that aspects of their subjects' health have been entrusted to them.

On our view, then, clinical researchers have limited entrustment responsibilities that emerge from three principal constitutive conditions: the permissions granted by subjects, their resulting vulnerability to researcher discretion, and this trio of generally applicable duties. Once these entrustment responsibilities are in place, they magnify and specify the contextual import of these three underlying duties. We will return to compassion, engagement, and gratitude below, but first we should look at the scope of the partial entrustment, which is tied to the first constitutive condition—the permissions granted.

Determining the Scope of the Partial Entrustment

Our analysis so far generates two questions that need to be addressed in the context of each research trial: What aspects of subjects' health have been entrusted to researchers? And how strong is the rationale for concluding that they have entrustment-based responsibilities to provide ancillary-care for those aspects of subjects' health? The answer to the first question fixes the *scope* of entrustment, while the answer to the second fixes the *strength* of the grounds for ascribing ancillary-care responsibilities.

Since medical researchers are not trustees, the entrustment responsibilities incumbent on them are limited in both scope and strength. That they are limited in scope means that not all types of medical care that a subject might need are part of the researchers'

responsibility. That they are limited in strengh means that in some contexts, the rationale for providing ancillary care is insufficient to justify spending the researchers' time and resources on it. That ancillary care falls within the scope of entrustment raises the question of responsibility; the strength of the rationale helps answer it. In our proposed framework, these aspects of scope and strength pair with the two elements of entrustment (discretion and vulnerability) as follows: the scope of ancillary-care responsibilities hinges on the range of permissions—and hence, indirectly, on the extent of discretion—that subjects give to researchers. The strength of these responsibilities centrally depends on the degree of subject vulnerability.

In a rough way, the initial scope of the entrustment involved in any given research project is set by the extent and nature of permissions that subjects grant researchers in the informed consent process: these are matters of public record and objective fact, not of psychology. The scope of entrustment is not set by what subjects hope or expect, nor by what they think they are entrusting to researchers. Rather, the initial scope of entrustment is fixed by the subset of the permissions obtained during the consent process that are required for the research team to carry out the study validly and safely.[19] Accordingly, the scope of entrustment depends in the first instance on the nature of the study. A study that requires only a one-time blood draw involves a minimal authorization, yielding a scope narrowed to focus on discretionary decisions pertaining to what that blood reveals. A long-term natural-history study of a rare and chronic disease may involve much fuller implicit grants of discretion, which flow from the broader permission subjects in such a study give researchers to collect information. The protocol will determine what sorts of information or samples will be needed, what procedures or interventions will be used, with what frequency, and over how long a period. It is the nature of the study that thus determines the initial scope of entrustment, not what the consent documents do or do not say about what ancillary care will be provided.

In the course of a trial, the scope of entrustment can be expanded if subjects implicitly grant and researchers implicitly accept additional permissions. For example, during the course of a long-term natural-history study of a rare condition, researchers may come to suspect that subjects' patterns of dentition may carry crucial information. Accordingly, they might begin asking the subjects to let them take a look at their teeth. This relatively minor further grant of discretion could justifiably take place without any modification of either the protocol or the consent documents; yet it may have implications for ancillary care since the examinations may incidentally uncover dental problems. This expansion of researchers' discretion should be distinguished from the evolution of the researchers' role, as sometimes happens when researchers gradually take on the additional role of being a subject's primary physician.[20] Our analysis remains focused on the responsibilities of researchers as such.

This analysis illuminates two important generalizations about the scope of researchers' responsibilities for ancillary care. First, insofar as conducting the study requires that researchers will be authorized to monitor or combat a particular disease or condition, providing care for that disease or condition will fall within the scope of their responsibilities. Second, insofar as conducting the study requires that researchers collect confidential medical information which may lead to clinically significant diagnoses, acting on those diagnoses will fall within the scope of their responsibilities. Depending on the context, appropriate follow-up might entail either that the research team provide treatment or only that they refer the subject to another provider.

Assessing the Strength of the Rationale

A patient's cancer brings him or her within the scope of an oncologist's domain, but whether the oncologist should pursue a treatment such as chemotherapy will depend on further factors, such as how effective or toxic the therapy might be. Analogously, if the permissions granted to researchers bring a type of ancillary care within the scope of what is entrusted, then it falls within the research team's moral concern, but whether there is a responsibility to provide this ancillary care will depend on further factors. In particular, limitations on financial and human resources and on the availability of potential subjects will almost always generate valid reasons not to provide a given type of ancillary care. Consequently, even if we assume that a given sort of ancillary care falls within the scope of entrustment, whether there is a responsibility to provide it will depend on how strong the case is for offering it, judged on the basis of the researchers' duties of compassion, engagement, and gratitude. The strength of the rationale for providing ancillary care thus depends in the first instance on the degree of subjects' vulnerability, past or future, and on the extent to which the duty of rescue reinforces these grounds.

The kind of subject vulnerability that lies at the core of the partial entrustment between researcher and subject stems from the fact that it will be affected by subjects' health how researchers exercise the discretion that subjects indirectly grant them. The first factor affecting the strength of the rationale for providing ancillary care, then, concerns the magnitude of this difference: How much difference would the provision of this care make to subjects' health and well-being? How threatened is their health? How well could the research team promote its threatened aspect? What other avenues do subjects have for seeking care?

The degree of vulnerability that subjects have accepted by enrolling in a study can affect the strength of the rationale for providing care even if it lies in the past. That is because the more subjects have been willing to expose themselves to possible risks or discomforts, the more researchers owe them a debt of gratitude; and the more that gratitude is owed, the stronger the case is for their entrustment responsibilities.

Considerations relevant to the duty of rescue can also affect the strength of the rationale for providing ancillary care. If only the research team is able to provide a given kind of care to the subject, or if it is predictable that no one else will provide it, the moral grounds for providing the care are reinforced. A proxy measure of the degree of uniqueness of the team's ability to help is the degree of subjects' dependency on their help. Subjects are dependent on researchers to the extent that they have to entrust some aspect of their health to the research team. Dependency of this kind can arise in various ways. Desperately ill people who turn to research protocols as their "last, best hope" are quite dependent upon the resulting relationship of entrustment. Desperately poor people who have no other source of medical care are also dependent on the relationship. And if participation in a study displaces a subject's previous sources of medical care, then the subjects can *become* dependent on a research team for their health care without the researchers having agreed to become their physicians. The more dependent subjects are, the closer researchers are to having a unique ability to help them, and hence the stronger their responsibilities for providing help.

As with the scope of entrustment, these strengthening factors will vary with the evolving depth and intensity of the relationship between a researcher and subject. As researchers and subjects interact and engage with one another over time, the relevant kinds of vulnerability and dependency may deepen. Some of these contextual variations will be morally arbitrary or even discriminatory, while others will be an appropriate basis for recognizing intensified ancillary-care responsibilities. Accordingly, in assessing the strength of the rationale for providing ancillary care, it is important to probe in some detail the changing nature of the relationship between researcher and subject.

Even if we assume that a given sort of ancillary care falls within the scope of entrustment, whether there is a responsibility to provide it will depend on how strong the case is for offering it, judged on the basis of the researchers' duties of compassion, engagement, and gratitude.

Application to Cases

These considerations imply the following framework for analyzing concrete claims for ancillary care. First, one must decide if a given type of ancillary care falls within the scope of the subjects' evolving, partial entrustment of their health to the researchers. If it does, then one must assess the degree to which researchers ought to devote human and financial resources to providing the care: this depends on the degree of subjects' vulnerability and dependency and on the seriousness of any debt of gratitude owed them.

Consider a hypothetical study of malaria in children in an area of Africa where malaria is endemic. These researchers will perform microbiological examination of urine samples. They can expect 10 percent of their child subjects to be infected with schistosomiasis and also that 10 percent of their child subjects will suffer from the sequelae of ill-treated road-accident injuries. Care for schistosomiasis is clearly within the scope of entrustment: the schistosomiasis will be diagnosed by the urinalysis that must be carried out under the research protocol, and appropriately responding to the diagnosis is therefore part of rightly using the discretion that subjects have implicitly granted to the researchers. In addition, the rationale for treating schistosomiasis is quite strong, as these children are typically in a vulnerable condition and whether the disease is treated will make a big difference to them. Since it would not hobble the research effort to treat the 10 percent of children in the study infected with schistosomiasis, they ought to be treated.[21]

But suppose the prevalence of schistosomiasis in the area were 90 percent rather than 10 percent. Depending on the study, treating schistosomiasis incidentally diagnosed during the study might now put an overwhelming burden on the research

team's budget. In such a case, it might be reasonable to conclude that, even though the ancillary care is within the scope and the reasons for providing it are strong, the countervailing reasons are compelling enough to limit the researchers' responsibilities to secondary steps, such as building the local infectious disease infrastructure.

What about the road-accident sequelae? The considerations of strength remain roughly the same. Care for these injuries is not within the scope of entrustment, however, at least when the common sequelae leave visible traces in limps or deformed limbs. These require no special permissions to diagnose and can be seen by anyone with the naked eye. Hence these researchers have no special responsibility to rectify these sequelae, whether or not it is within their competence to do so.

Now consider a functional brain imaging study conducted on healthy volunteers at a medical research hospital in the United States, with the intention of discovering what parts of the brain are active when subjects undertake specified neurological tasks. Assume that the study requires that a radiologist read these scans. Should these images also be read diagnostically? Certainly diagnostic reading is within the scope of entrustment. Subjects have given permission for the images to be taken, and the diagnostically relevant information is already contained in them. The question is how the research team will exercise its discretion in handling that information. Although only perhaps 1 percent of "normals" will have scans that would generate an urgent need for referral,[2] [2] the potentially life-threatening character of the tumors or aneurisms that might be detected make the rationale for providing ancillary care quite strong. The additional demand on the radiologist's time does not seem significant enough to defeat these considerations. Functional brain imaging researchers therefore generally have a responsibility to do diagnostic readings of brain scans and to follow up appropriately.

The partial-entrustment model reflects an underlying conception of the professional role of someone doing medical research on human subjects as *sui generis*, not reducible to that of either personal physician or mere scientist.

These cases illustrate the middle position on researchers' responsibilities for ancillary care taken by the partial-entrustment model. One polar position, casting researchers as personal physicians, would demand too much ancillary care and set the scope of researchers' responsibilities too broadly. The other polar position, casting researchers as mere scientists, would demand too little care and set the scope of their ancillary care responsibilities too narrowly. The partial-entrustment model, supporting a definite but limited set of responsibilities, reflects an underlying conception of the professional role of someone doing medical research on human subjects as *sui generis*, not reducible to that of either personal physician or mere scientist. The scope of the entrustment depends on the nature of each study, and specifically on the needed range of permissions that subjects grant researchers. The rationale for providing care that falls within the scope is strongest when subjects are particularly vulnerable to how researchers exercise their discretion, are particularly dependent on the researchers for care, or have been particularly willing to offer themselves up for risky, painful, or inconvenient studies without reward to themselves. In impoverished settings, where researchers may have rare abilities to provide urgently needed help, the duty to rescue that is incumbent on everybody will expand researchers' responsibilities for ancillary care, but still not without limit.

Although this framework provides a systematic way to think through researchers' responsibilities for ancillary care, ancillary-care responsibilities will need to be considered in detail every time a protocol is proposed. Since it is generally desirable for researchers to be clear up front about the kinds of ancillary care they will and will not provide to their subjects, it is also their responsibility, with the help and guidance of institutional review boards, to attempt to estimate the types of ancillary care that a given study will provide. To the extent that foresight allows, protocols and consent documents should incorporate a statement detailing this ancillary-care. Individual researchers, IRBs, sponsors of research, and policymakers must attend to the strong moral reasons for offering certain types of ancillary care even if doing so makes research somewhat more complicated and costly than it would otherwise be. On the partial-entrustment model we have presented and defended, researchers' responsibilities for providing ancillary-care are delimited but no less real for that.

Acknowledgements

We are grateful to many rounds of help from Ezekiel Emanuel, Christine Grady, Frank Miller, Leif Wenar, and David Wendler, and also to audiences at the Parasitology and International Programs Branch at NIAID; the Department of Clinical Bioethics; the 3rd Africa Conference on Ethical Aspects of Clinical Research in Developing Countries; and the Kennedy Institute of Ethics. The opinions expressed in this article are the authors' and do not reflect those of the Department of Clinical Bioethics, the National Institutes of Health, the Public Health Service, or the Department of Health and Human Services.

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8. See the Canadian Supreme Court's useful statement of these principles in *Hodgkinson v. Simms* [1994] 3 S.C.R. 377, citing *Frame v. Smith* [1987] 2 S.C.R. 99. We are grateful to Ambrose Talisuna for this reference. In "Trust and Antitrust," *Ethics* 96 (1986): 231-60, esp. 236-40, Annette Baier emphasizes the discretion and vulnerability involved in entrustment. Partly because she intends her account of entrustment as a basis for understanding trust more generally, she does not distinguish as we do between grants of discretionary authorization and simply placing one's head inside the lion's jaws.

9. The idea of bailment has thus been explored in the context of ethical principles pertaining to the use of stored tissues. See K. Gottlieb, "Human Biological Samples and the Laws of Property: The Trust as a Model for Biological Repositories," in *Stored Tissue Samples: Ethical, Legal, and Public Policy Implications,* ed. R.F. Weir (Iowa City: University of Iowa Press, 1998): 182-97. We are grateful to Heidi Li Feldman for steering us to bailment.

10. On the difficulty of eliminating this element of discretion from entrustment relationships, see Baier, "Trust and Antitrust," 237n. and 250.

11. Bailment-type responsibilities are incurred voluntarily, by accepting certain permissions, even though the extent of the resulting responsibilities is not set by the parties' concurring wills. In general, we do not believe that all special obligations must be voluntarily undertaken. We would generalize the argument against such voluntarism that appears in M.O. Hardimon, "Role Obligations," *Journal of Philosophy* 94 (1994): 333-63.

12. On the importance of vulnerability to entrustment responsibilities that go beyond contract, see P.C. Flynn, "Ethics in the Board Room: Contracts or Fiduciary Relationships?" *Philosophy in the Contemporary World*, 10 (2003): 43-48.

13. These discretionary judgments are not unilateral, for any treatment decision must generally be reached in dialogue with the subject; but in that dialogue, the researcher owes the subject an expression of his or her best professional judgment.

14. This is shown by the case of selling a patent to one's competitor, who thus gains a discretionary power to use it in ways that might hurt one's business. Such a purchaser is not burdened by any entrustment obligation.

15. We focus on the duty to behave in a compassionate manner, or as if one felt compassion. Whether this duty entails (conceptually or as a necessary means) that one actually feel compassion we leave to one side.

16. This requirement could be understood as an implication, in situations of more than usual intimacy, of the general duty of respect for persons. See O. O'Neill, "Between Consenting Adults," *Philosophy and Public Affairs* 14 (1985): 252-77, esp. 270-72. We thank Nir Eyal for this reference.

17. E.D. Pellegrino, "Nonabandonment: An Old Obligation Revisited," *Annals of Internal Medicine* 122, no. 5 (1995): 377-78.

18. Miller, Rosenstein, and DeRenzo, "Professional Integrity in Clinical Research."

19. Extraneous permissions collected in the informed consent process will not expand the scope of ancillary-care responsibilities.

20. When such evolution takes place, care must be taken to preclude confusion: see F.G. Miller and D.L. Rosenstein, "The Therapeutic Orientation to Clinical Trials," *NEJM*348 (2003): 1383-86.

21. According to a WHO Executive Board report, each treatment of schistosomiasis with praziquantel costs only between 20 and 30 cents. "Communicable Diseases: Control of Schistosomiasis and Soil-transmitted Helminth Infections," EB107/31, 27 October 2000.

22. G.L. Katzman, A.P. Dagher, and N.J. Patronas, "Incidental Findings on Brain Magnetic Resonance Imaging from 1000 Asymptomatic Volunteers," *JAMA* 282 (1999): 36-39.